

5 **Claims:**

 WHAT IS CLAIMED IS:

1. An aqueous triptan formulation suitable for intranasal administration of a triptan comprised of a triptan, water, and an absorption enhancer wherein the triptan formulation has a t_{max} in serum of less than 15 minutes after intranasal
10 administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.
2. The aqueous triptan formulation of claim 1 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan,
15 zolmitriptan, eletriptan and sumatriptan.
3. The aqueous triptan formulation of claim 1 wherein the absorption enhancer is a cyclodextrin.
- 20 4. The aqueous triptan formulation of claim 3 wherein the absorption enhancer is α -cyclodextrin.
5. The aqueous triptan formulation of claim 3 wherein the triptans are selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan,
25 zolmitriptan, eletriptan and sumatriptan.
6. The aqueous triptan formulation of claim 5 wherein the triptan present in the formulation is sumatriptan.
- 30 7. The aqueous triptan formulation of claim 6 further comprised of a preservative.

5 8. The aqueous triptan formulation of claim 1 wherein the absorption enhancer is chitosan.

9. The aqueous triptan formulation of claim 6 wherein the sumatriptan is present in the aqueous formulation at a concentration of about 4% weight/weight, and the
10 alpha-cyclodextrin is present at a concentration of about 5% wt/wt.

10. The aqueous triptan formulation of claim 9 further comprised of a chelating agent.

11. The aqueous triptan formulation of claim 6 wherein the sumatriptan is present in the aqueous formulation at a concentration of about 25% wt/wt and the alpha-cyclodextrin is present at a concentration of about 5% wt/wt.
15

12. The aqueous triptan formulation of claim 1 wherein the absorption enhancer is chitosan.

20

13. An aqueous triptan formulation suitable for intranasal administration of a triptan comprised of a triptan, water, and an absorption enhancer wherein the triptan reaches a mean plasma concentration of at least 1.5 ng of triptan per mL of plasma within 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.
25

30

14. The aqueous triptan formulation of claim 12 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

5 15. The aqueous triptan of claim 13 wherein the absorption enhancer is a cyclodextrin.

16. The aqueous triptan formulation of claim 15 wherein the absorption enhancer is α -cyclodextrin.

10

17. The aqueous triptan formulation of claim 12 wherein the triptan reaches a mean plasma concentration of at least 1.8 ng of triptan per milliliter of plasma within 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.

15

18. The aqueous triptan formulation of claim 14 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

20 19. The aqueous triptan formulation of claim 12 wherein the triptan reaches a mean plasma concentration of at least 2.0 ng of triptan per milliliter of plasma within 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.

25 20. The aqueous triptan formulation of claim 16 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

30 21. An aqueous triptan formulation suitable for intranasal administration of a triptan comprised of a triptan, water, and an absorption enhancer wherein the triptan formulation has a mean partial areas under the curve for the first 20 minutes after

5 intranasal administration of a sufficient amount of the formulation to deliver 5 mg
of the triptan to the nose of at least 25 ng per minute per mL of serum.

10 22. The aqueous triptan formulation of claim 18 wherein the triptan is selected from
the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan,
zolmitriptan, eletriptan and sumatriptan.

15 23. The aqueous triptan formulation of claim 18 wherein the triptan formulation has a
mean partial area under the curve for the first 20 minutes after intranasal
administration of a sufficient amount of the formulation to deliver 5 mg of the
triptan to the nose of at least 30 ng per minute per mL of serum.

20 24. The aqueous triptan formulation of claim 20 wherein the triptan is selected from
the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan,
zolmitriptan, eletriptan and sumatriptan.

25 25. An aqueous triptan formulation suitable for intranasal administration of a triptan
comprised of a triptan, water, and an absorption enhancer wherein the triptan
formulation has a mean absorption rate of less than 20 minutes after intranasal
administration of a sufficient amount of the formulation to deliver 5 mg of the
triptan to the nose.

30 26. The aqueous triptan formulation of claim 22 wherein the triptan is selected from
the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan,
zolmitriptan, eletriptan, and sumatriptan.

- 5 27. The aqueous triptan formulation of claim 22 wherein the triptan formulation has a mean absorption rate of less than 15 minutes after intranasal administration of 5 mg of the triptan.
- 10 28. An aqueous triptan formulation suitable for intranasal administration of a triptan comprised of a triptan, water, and an absorption enhancer wherein the triptan formulation has a mean Cmax of at least 1.5 ng of triptan per mL of serum 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.
- 15 29. An aqueous triptan formulation suitable for intranasal administration of a triptan comprised of water, a cyclodextrin and one or more triptans selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan eletriptan and sumatriptan.
- 20 30. The aqueous triptan formulation of claim 29 wherein the cyclodextrin is alpha-cyclodextrin.
31. The aqueous triptan formulation of claim 29 further comprised of a preservative.
- 25 32. The aqueous triptan formulation of claim 29 further comprised of a chelating agent.
33. The aqueous triptan formulation of claim 32 wherein the chelating agent is ethylene diamine tetraacetic acid (EDTA).

5 34. The aqueous triptan formulation of claim 30 wherein the triptan is sumatriptan and is present in the aqueous formulation at a concentration of about 4% weight/weight, and the alpha-cyclodextrin is present at a concentration of about 5% wt/wt.

10 35. The aqueous triptan formulation of claim 30 wherein the sumatriptan is present in the aqueous formulation at a concentration of about 25% wt/wt and the alpha-cyclodextrin is present at a concentration of about 5% wt/wt.

15 36. An aqueous sumatriptan formulation comprised of water, sumatriptan and alpha-cyclodextrin.

20 37. A method of treating a migraine headache comprising intranasally administering an aqueous triptan formulation wherein the formulation is comprised of a triptan, water, and an absorption enhancer wherein the triptan formulation has a tmax in serum of the triptan of less than 15 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.

25 38. The method of claim 37 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

39. The method of claim 37 wherein the absorption enhancer is a cyclodextrin.

40. The method of claim 39 wherein the absorption enhancer is α -cyclodextrin.

30

- 5 41. The method of claim 39 wherein the triptans are selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.
- 10 42. The method of claim 41 wherein the triptan present in the formulation is sumatriptan.
43. The method of claim 42 wherein the formulation is further comprised of a preservative.
- 15 44. The method of claim 37 wherein the absorption enhancer is chitosan.
45. The method of claim 42 wherein the sumatriptan is present in the aqueous formulation at a concentration of about 4% weight/weight, and the absorption enhancer is alpha-cyclodextrin present at a concentration of about 5% wt/wt.
- 20 46. The method of claim 45 wherein the aqueous formulation is further comprised of a chelating agent.
47. The method of claim 42 wherein the sumatriptan is present in the aqueous formulation at a concentration of about 25% wt/wt and the absorption enhancer is alpha-cyclodextrin present at a concentration of about 5% wt/wt.
- 25 48. The method of claim 37 wherein the absorption enhancer is chitosan.
49. A method for treating a migraine headache comprised of intranasally administering to an individual an aqueous triptan formulation comprised of a
- 30

5 triptan, water, and an absorption enhancer wherein the triptan reaches a mean plasma concentration of at least 1.5 ng of triptan per mL of plasma within 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.

10 50. The method of claim of claim 49 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

51. The method of claim 49 wherein the absorption enhancer is a cyclodextrin.

15

52. The method of claim 51 wherein the cyclodextran is α -cyclodextrin.

53. The method of claim 49 wherein the triptan reaches a mean plasma concentration of at least 1.8 ng of triptan per milliliter of plasma within 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.

20

54. The method of claim 53 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

25

55. The method of claim 49 wherein the triptan reaches a mean plasma concentration of at least 2.0 ng of triptan per milliliter of plasma within 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.

30

5 56. The method of claim 55 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

10 57. A method for treating a migraine headache in an individual comprising intranasally administering to the individual an aqueous triptan formulation comprised of a triptan, water, and an absorption enhancer wherein the triptan formulation has a mean partial areas under the curve for the first 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose of at least 25 ng per minute per mL of serum.

15 58. The method of claim 57 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

20 59. The method of claim 57 wherein the triptan formulation has a mean partial area under the curve for the first 20 minutes after intranasal administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose of at least 30 ng per minute per mL of serum.

25 60. The method of claim 59 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan and sumatriptan.

30 61. A method for treating a migraine headache in an individual comprising intranasally administering to the individual an aqueous triptan formulation comprised of a triptan, water, and an absorption enhancer wherein the triptan formulation has a mean absorption rate of less than 20 minutes after intranasal

5 administration of a sufficient amount of the formulation to deliver 5 mg of the triptan to the nose.

62. The method of claim 61 wherein the triptan is selected from the group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan, eletriptan, and
10 sumatriptan.

63. The method of claim 61 wherein the triptan formulation has a mean absorption rate of less than 15 minutes after intranasal administration of 5 mg of the triptan.

15 64. A method for treating a migraine headache in an individual comprising intranasally administering to the individual an aqueous triptan formulation comprised of a triptan, water, and an absorption enhancer wherein the triptan formulation has a mean Cmax of at least 1.5 ng of triptan per mL of serum 20 minutes after intranasal administration of a sufficient amount of the formulation
20 to deliver 5 mg of the triptan to the nose.

65. A method for treating a migraine headache in an individual comprising intranasally administering to the individual an aqueous triptan formulation comprised of water, a cyclodextrin and one or more triptans selected from the
25 group consisting of naratriptan, almotriptan, frovatriptan, rizatriptan, zolmitriptan eletriptan and sumatriptan.

66. The method of claim 65 wherein the cyclodextrin is alpha-cyclodextrin.

30 67. The method of claim 65 wherein the formulation is further comprised of a preservative.

5

68. The method of of claim 65 wherein the formulation is further comprised of a chelating agent.

10

69. The method of claim 68 wherein the chelating agent is ethylene diamine tetraacetic acid (EDTA).

15

70. The method of claim 65 wherein the triptan present in the formulation is sumatriptan at a concentration of about 4% weight/weight, and the cyclodextrin is alpha-cyclodextrin at a concentration of about 5% wt/wt.

20

71. The method of claim 65 wherein the triptan contained in the formulation is sumatriptan and is present in the aqueous formulation at a concentration of about 25% wt/wt and the cyclodextrin is alpha-cyclodextrin and is present at a concentration of about 5% wt/wt.

25

72. A method for treating a migraine headache in an individual comprising intranasally administering to the individual an aqueous sumatriptan formulation comprised of water, sumatriptan and alpha-cyclodextrin.

73. The method of claim 72 wherein the alpha-cyclodextrin is present in the formulation at a concentration of about 5% w/w.